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REMARKS

Claims 1-8, 11-17 and 20-27 are pending in this application. No claim amendments are made herein. Reconsideration of the pending claims is requested.

Claim Rejections under 35 U.S.C. §103:

Claims 1-8, 11-17 and 20-27 have been rejected under 35 U.S.C. §103 as allegedly being unpatentable over Yabusaki, U.S. Pat. No. 4,738,932 ("Yabusaki") in view of Avanti Polar Lipids product no. 710332 ("Avanti 710332") and further in view of Avanti Polar Lipids product no. 850457 ("Avanti 850457"). Four separate §103(a) rejections were issued (see, paragraphs 15, 16, 19, and 20 of the final Office Action, mailed December 3, 2003); however, each rejection cites the same above-mentioned combination of references and each rejection is supported by the same justification. Thus, Applicants provide a collective response to all of the obviousness rejections. Applicants continue to traverse each of the §13(a) rejections for the reasons set forth in the Amendment and Response to Non-final Office Action, mailed August 28, 2003, and the Amendment and Response to Final Office Action, mailed March 2, 2004 (collectively, the "prior responses").

Applicants believe the Office has not established a *prima facie* case of obviousness for all the reasons stated in the prior responses. As previously noted, the prior art does not suggest the claimed combination and, in fact, teaches away from it. For example, the prior art at the time of the invention showed that antigens including synthetic cardiolipin *or* synthetic lecithin provided unpredictable results in syphilis serological tests. In light of the unpredictability resulting from use of any synthetic antigen in such tests, the art at the time of the invention did not even contemplate a combination of a synthetic cardiolipin *and* a synthetic lecithin. Thus, even if there were a motivation to combine the cited references (which is not conceded), there was no reasonable expectation that the combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine would be a successful antigenic composition. For at least this reason, the Office has failed to establish a *prima facie* case of obviousness.

However even if a *prima facie* case of obviousness had been established, Applicants have previously provided *experimental evidence from the specification* showing that the claimed

combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine provides unexpectedly superior specificity and sensitivity in syphilis serological tests as compared to the combination of naturally occurring cardiolipin and naturally occurring lecithin described in Yabusaki. Such unexpectedly superior results would rebut any *prima facie* case of obviousness with respect to the claimed combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine. The Office characterizes the data demonstrating unexpected superiority (provided in the Amendment and Response to Final Office Action, mailed March 2, 2004) as "arguments of counsel" (see paragraph 5(a) of the Advisory Action, mailed April 22, 2004). Applicants disagree with this characterization of actual experimental results that were discussed in the March 2, 2004 response. Nonetheless, Applicants provide herewith a Declaration under 37 C.F.R. §1.132, which further demonstrates the unexpectedly superior selectivity and sensitivity of the claimed antigenic composition comprising tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine.

The attached Declaration under 37 C.F.R. §1.132 provides experimental evidence showing that numerous other combinations of synthetic cardiolipin and synthetic lecithin *cannot* substitute for naturally occurring cardiolipin and lecithin in syphilis serological testing. The unsuitability of these many synthetic analogs for serological syphilis testing reaffirms that there is no reasonable expectation that tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine could be combined to form a successful antigenic composition. Moreover, it shows that the prior art at the time of the invention taught away from synthetic antigens for syphilis testing because such antigens were less effective than an antigen composed of naturally occurring cardiolipin and lecithin. Further, the unsuitability of these many synthetic analog combinations emphasizes the unpredictability of such combinations, which further demonstrates that the selection of the successful combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine is unexpectedly superior and non-obvious.

The attached Declaration further shows that, in a side-by-side comparison of reactivity with syphilitic sera, the claimed antigen composition (comprising tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine) was not only as reactive (*i.e.*, sensitive), but was often more reactive, than an antigen composed of naturally occurring cardiolipin and lecithin

(such as, that cited by the Office action in Yabusaki). Each result was unexpected and surprising in view of the many past failures using other synthetic antigens (as described above). The attached Declaration also shows that fewer false negative results are obtained in syphilis serological tests using the claimed antigen composition (comprising tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine) as compared to an antigen composed of naturally occurring cardiolipin and lecithin. Such superior selectivity had not previously been demonstrated for a synthetic antigen composition and was, again, particularly surprising and unexpected in view of past failures of other synthetic antigens (as described above).

In view of the unexpectedly superior sensitivity and selectivity of the claimed combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine, each of the obviousness rejections directed to the composition claims (*i.e.*, claims 1-8, 11, and 22-24) should be withdrawn. In addition, methods of using the novel and non-obvious antigen composition should similarly be allowable; therefore, each of the obviousness rejections directed to the method claims (*i.e.*, claims 12-17, 20, 21, and 25-27) should be withdrawn.

Paragraph 5(b) of the Advisory Action, mailed April 22, 2004

The Advisory Action alleges in paragraph 5(b) that "the prior art at the time of the invention . . . encourages the use of synthetic cardiolipin and lecithin in diagnosing syphilis (see attached article)." The "attached article" referred to in the Advisory Action was not attached to the papers delivered to Applicants. Therefore, the basis for the Office's statement that the prior art encouraged the use of synthetic components is unclear.

As discussed in the prior responses and in the Declaration attached hereto, the prior art at the time of the invention demonstrates that synthetic analogs of cardiolipin and lecithin could not be predictably substituted for naturally occurring cardiolipin and lecithin without loss of antigen activity. The evidence, therefore, does not support the allegation in the Advisory Action that the prior art "encourages the use of synthetic cardiolipin and lecithin." Instead, the unpredictable activity of antigen compositions containing synthetic cardiolipin or synthetic lecithin actually

taught away from the combination of Yabusaki, Avanti 710332, and Avanti 850457. For this further reason, each of the obviousness rejections should be withdrawn.

Paragraph 5(c) of the Advisory Action, mailed April 22, 2004

The Advisory Action alleges that "[i]t is prima facie obvious to combine two compositions *each of which is taught by the prior art to be useful for the same purpose*" (emphasis added). The Office fails to explain how Yabusaki (or any other prior art) shows that tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine are useful for the same purpose as naturally occurring cardiolipin and lecithin. In fact, as discussed above and in the previous responses, the prior art was replete with examples where other antigens comprising synthetic cardiolipin or synthetic lecithin were *not* as useful as the naturally occurring compounds for the same purpose. The selection and combination of the two claimed synthetic analogs provided an antigen having unpredictably increased sensitivity and specificity as compared to the antigen composed of naturally occurring cardiolipin and lecithin and the many other synthetic antigens that were tested.

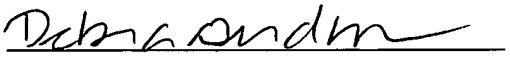
CONCLUSION

For all of the foregoing reasons, each of the obviousness rejections should be withdrawn. The evidence of record demonstrates the unpredictability in the art of selecting combinations of synthetic cardiolipin and lecithin analogs for detecting anti-lipoidal antibodies in syphilis serological tests. Prior efforts to use antigens having even one (much less two) synthetic component(s) in syphilis serologic tests have produced disappointing results because such antigens have been found to be less sensitive than an antigen composed of naturally occurring cardiolipin and lecithin. In contrast to the prior art, the specific claimed combination of synthetic cardiolipin and lecithin analogs provides an assay with sensitivity and specificity that is greater than that obtained with the antigen composed of natural components or the other tested synthetic antigens. The claimed combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine is therefore non-obvious in view of the prior art.

It is respectfully submitted that the present claims are in a condition for allowance. If it may further issuance of these claims, the Examiner is invited to call the undersigned patent attorney at the telephone number listed below.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By 
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Pope *et al.*

Application No. 10/009,698

Filed: December 5, 2001

Confirmation No. 1330

For: COMPOSITIONS AND METHODS FOR DETECTING SYPHILIS USING SYNTHETIC ANTIGENS

Examiner: Khatol S. Shahnan Shah

Art Unit: 1645

Attorney Reference No. 6395-61750-01

DECLARATION OF VICTORIA POPE, PH.D. UNDER 37 C.F.R. §1.132

1. I, Victoria Pope, Ph.D., am a co-inventor of the above-referenced patent application. I am currently the Chief, Syphilis Serology Reference Laboratory, Sexually Transmitted Infections Branch, Division of AIDS, STD, and TB Laboratory Research, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, and have been doing scientific research for about 30 years. I have been involved in research related to the serological detection of syphilis for much of my career. My Curriculum Vitae is attached as Exhibit A.

2. I have read and understood the above-referenced patent application, including the pending claims. I have also each read and understood the Office action, dated December 3, 2003, and the Advisory Action, dated April 22, 2004.

3. It is my understanding that claims 1-8, 12-17, and 20-27 have been rejected as allegedly being unpatentably obvious in view of the combination of Yabusaki, U.S. Pat. No. 4,738,932 ("Yabusaki"), Avanti Polar Lipids product no. 710332 ("Avanti 710332"), and Avanti Polar Lipids product no. 850457 ("Avanti 850457"). In addition, it is my understanding that the rejection was made on the ground that it would be obvious to one of skill in the art to substitute commercially available tetramyristoyl cardiolipin (Avanti 710332) and commercially

available 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine (Avanti 850457) for naturally occurring cardiolipin and naturally occurring lecithin in the antigen composition set forth in Yabusaki (the "VDRL antigen").

4. The combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine provides an unexpectedly superior antigen composition when compared to the VDRL antigen described in Yabusaki. These unexpectedly superior results are demonstrated in the specification of the above-referenced application and as described below.

5. The VDRL antigen (as described, for example, in Yabusaki) has numerous disadvantages. For example, naturally occurring cardiolipin is actually a mixture of compounds, each compound having a different complement of fatty acid side chains. The same is also true of naturally occurring lecithin. The fatty acid side chains comprising naturally occurring cardiolipin and naturally occurring lecithin differ in each biological source (at least because each biological source is genetically different and/or is raised under different environmental conditions). Therefore, each preparation of naturally occurring cardiolipin and lecithin is different. As a result, it is believed that there is no feasible way to make a standardized VDRL preparation. In addition, the natural antigen can also be unstable because unsaturated fatty acids in naturally occurring cardiolipin and naturally occurring lecithin can be oxidized.

6. For years, researchers have been *unsuccessfully* trying to replace naturally occurring cardiolipin and naturally occurring lecithin in the VDRL antigen with synthetic compounds offering at least the same properties. For example, the following synthetic cardiolipin and lecithin analogues were studied in combination with the naturally occurring counterpart compound by Baer and Kates (*Science*, 109:31, 1949), Tonks and Allen (*Science*, 118:55, 1953), and Inoue and Nojima (*Biochim. Biophys. Acta*, 144(2):409, 1967):

Cardiolipin

1. tetramyristoyl-bis-(L-a-glyceryl) phosphoric acid.
2. bis (dipalmitoyl D,L-a-glycerylphosphoryl)-1,3 glycerol benzyl ether disodium salt.
3. bis (dipalmitoyl D,L-a-glycerylphosphoryl)-l,5 pentanediol disodium salt.
4. bis (dipalmitoyl D.L-a-glycerylphosphoryl)-1,3 propanediol disodium salt.
5. bis (dipalmitoyl D,L-a-glycerylphosphoryl)-1,4 butanediol disodium salt.
6. bis (dipalmitoyl D,L-a-glycerylphosphoryl)-1,2 ethanediol disodium salt.

7. bis (dipalmitoyl D,L-a-glycerylphosphoryl)-methanediol disodium salt.
8. bis (dipalmitoyl D,L-a-glycerylphosphoryl)-1,3 glycerol disodium salt.
9. bis (benzylphosphoryl)-1,3-propanediol disodium salt.
10. D,L-a-dipalmitoyl bis-phosphatidic acid.

Lecithin

1. DL-a-dimyristoyl lecithin.
2. L-a-dimyristoyl cephalin.
3. L-a-dipalmitoyl lecithin.
4. dipalmitoyl L-a-glycerophosphoric acid monocholine salt.
5. L-a-dimyristoyl lecithin.
6. D-a-dimyristoyl lecithin.
7. L-a-distearoyl lecithin.
8. Stearoyl glycollecithin.

These reports showed that antigens made with the foregoing compounds in combination with their naturally occurring counterparts (*e.g.*, synthetic lecithin with naturally occurring cardiolipin and visa versa) were significantly less sensitive than the VDRL antigen.

7. In agreement with the results shown in paragraph 6, my co-inventors and I found that substitution of 1,1',2,2'-tetra-acyl-cardiolipin (tetraoleoyl 18:1) for naturally occurring cardiolipin in the VDRL antigen resulted in loss of antigen activity. Specifically, the results shown in Exhibit B demonstrate that the activity of an antigen containing 1,1',2,2'-tetra-acyl-cardiolipin (tetraoleoyl 18:1) and naturally occurring lecithin ("Pilot I antigen") was less than the activity of the VDRL antigen ("CDC 97-0036") at the same serum dilution using two different syphilitic sera ("CDC 97-0014" and "CDC #97"). In these results (and others described in this Declaration), the following six-point grading scale (from most reactive to non-reactive) was used: R, R(-),W(+),W, W(-), and N (or NR). Thus, data from us and others indicated that synthetic cardiolipins were not equivalent to naturally occurring cardiolipin in the VDRL antigen because antigens containing the synthetic cardiolipins had reduced activity.

8. Despite the contrary teaching in the art, we continued to examine other synthetic cardiolipin analogs. As further shown in Exhibit B, we unexpectedly discovered that the activity of an antigen including tetramyristoyl cardiolipin (*i.e.*, 1,1',2,2'-tetra-acyl-cardiolipin

(tetramyristoyl 14:0)) and naturally occurring lecithin ("Pilot II" antigen) was greater than that of the VDRL antigen using two different syphilitic sera ("CDC 97-0014" and "CDC #97").

9. Given our surprising discovery that tetramyristoyl cardiolipin was unexpectedly superior to naturally occurring cardiolipin in the VDRL antigen (see paragraph 8), we next determined the effect of combining synthetic lecithins with tetramyristoyl cardiolipin. We examined the following symmetric synthetic lecithins:

1. 1,2-dioleoyl-sn-glycero-3-phosphocholine (18:1)
2. 1,2-dilinoleoyl-sn-glycero-3-phosphocholine (18:2)
3. 1,2-dimyristoyl-sn-glycero-3-phosphocholine (14:0)
4. 1,2-dipentadecanoyl-sn-glycero-3-phosphocholine (15:0)
5. 1,2-diphytanoyl-sn-glycero-3-phosphocholine (16:0)
6. 1,2-dipalmitoyl-sn-glycero-3-phosphocholine (16:0)

As shown in Exhibit C, antigens comprising tetramyristoyl cardiolipin and each of the foregoing synthetic lecithins were less reactive than the VDRL antigen ("CDC 97-0036N") at the same serum dilution.

10. As discussed above, the fatty acid composition of naturally occurring lecithin is a mixture of saturated and unsaturated fatty acid chains of varying lengths; therefore, we examined over 30 mixtures of the synthetic lecithins described in paragraph 9 in combination with tetramyristoyl cardiolipin. Antigens having mixtures of synthetic lecithin were no better at detecting syphilitic serum than were the individual synthetic lecithins in combination with tetramyristoyl cardiolipin.

11. Despite recurring negative results (as described above), we continued to examine other synthetic lecithins in combination with tetramyristoyl cardiolipin. We unexpectedly discovered that the combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine surprisingly was not less effective than the VDRL antigen, but even more surprisingly was *more effective* than the VDRL antigen. Raw data demonstrating the unexpected superiority of the combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine are provided in Exhibit D. In particular, the page marked "23" shows that an antigen comprising 0.03% tetramyristoyl cardiolipin and 0.14% 1-palmitoyl-

2-oleoyl-*sn*-glycero-3-phosphocholine was at least as reactive, and often more reactive, with 20 non-frozen syphilitic serum samples (NT-1 to NT-20) and 20 frozen syphilitic serum samples (F-1 to F-20) than was the standard VDRL antigen ("Antigen CDC 97-0036N"). The pages marked "28" and "29" show more dilute end-point titres for 89.5% of serum samples tested (n=29) using an antigen comprising tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine as compared to the standard VDRL antigen. This means that it takes less of the combination of tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine than the VDRL antigen to detect syphilitic antibodies. Taken together, the data in this paragraph show that the synthetic antigen was qualitatively and quantitatively more sensitive than the standard VDRL antigen.

12. Exhibit D (page marked "32") shows that standard VDRL antigen (columns labeled "CDC") was much more likely to give a false negative reaction than was an antigen comprising tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine (columns labeled "Card 0.02%, Lecit. 0.11%" and "Card 0.03%, Lecit. 0.14%"). Fifty-two serum samples were tested for the presence of antibodies specific for the *T. pallidum* organism (referred to as "treponemes") (see columns labeled "MHA-TP"). The presence of antibodies to treponemes is indicated by a number between 1 and 4+ in the "MHA-TP" column. For numerous of the treponeme antibody-positive sera, the standard VDRL antigen showed no reaction ("N" or "NR" in the columns labeled "CDC"); for example, see serum samples 1, 3, 4, 8, 9, 11-13, 15, 17-21, 23, 25-27, 29, 32-34, 36, 38, 39, 44, 45, 48-50, 57 and 60. In comparison, our synthetic antigen tested positive for each of these samples. Thus, our synthetic antigen more accurately identifies treponeme antibody-positive sera than does the standard VDRL antigen.

13. The specification of the above-referenced application provides further experimental data derived from studies having even larger sample sizes. For example, when tested against serum reactive by the RPR Test (a standard, non-treponemal test for syphilis), the claimed synthetic antigen reacted with 100% of samples, while the naturally occurring antigen reacted with 88% of samples (see, for example, page 22, lines 1-4 of the specification). In quantitative testing, the claimed synthetic antigen had endpoint titres of 1/2 or 1 dilution better than the naturally occurring antigen in 85% of serums tested (see, for example, page 23, lines

12-14 of the specification). In blind testing of 495 serum specimens, the synthetic antigen was reactive with the same 38 samples that tested positive in tests for antibodies against the syphilis-causing bacteria, *Treponema pallidum*. In comparison, the naturally occurring antigen identified only 36 of the 38 treponeme antibody-positive cases (see, for instance, Example 7 of the specification).

14. Taken together, all of the foregoing facts evidence the superior reactivity and sensitivity of an antigen composition comprising tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine. This result is unexpected because, as discussed in detail herein, the prior art and our own work demonstrates that antigens including synthetic analogs of cardiolipin or lecithin are generally less sensitive (and certainly not more sensitive) than an antigen comprising naturally occurring cardiolipin and lecithin (*i.e.*, the VDRL antigen).

15. In addition to having unexpectedly superior reactivity and sensitivity (as described above), the synthetic antigen we discovered is also distinguishable from, and superior to, the VDRL antigen because the fatty acid side chains of tetramyristoyl cardiolipin are fully saturated and are not prone to oxidation under ordinary circumstances. Therefore, tetramyristoyl cardiolipin is more stable than its naturally occurring counterpart in the VDRL antigen.

16. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Victoria Pope, Ph.D.

May 19, 2004
Date

Exhibit A

Curriculum Vitae of Victoria Pope, Ph.D.

[see attached 11 pages]

Victoria Pope, Ph.D.
C.V.

CURRICULUM VITAE

Name: Victoria Pope
Home Address: P.O. Box 418, Hoschton, Georgia 30548-0418
Phone: Work (404) 639-3224; Home [redacted]
E-mail: vxp1@cdc.gov

Educational Background:

Degree	Date	Institution
B.S.	1969	Bowling Green State University, Bowling Green, Ohio (Major Biology)
MT(ASCP)	1970	Kettering Med. Ctr. School of Medical Technology, Kettering, Ohio
M.S.	1980	Georgia State University, Atlanta, Georgia (Major Microbiology) Masters Thesis: Evaluation of the enzyme-linked immunosorbent assay as an aid in the diagnosis of syphilis.
Ph.D.	1990	University of Minnesota, Minneapolis, Minnesota (Major Microbiology) Ph.D. Thesis: Numerical analysis of leptospiral sodium dodecyl sulfate-polyacrylamide gel electrophoresis patterns for determination of phenotypic relatedness.

Professional Experience:

1996 - Present. Microbiologist, Chief, Syphilis Diagnostic Immunology Activity, Syphilis/Chlamydia Research Branch, Division of AIDS, STD, and TB Laboratory Research, National Center for Infectious Diseases, Centers for Disease Control and Prevention

Primary responsibilities include supervising 5 full-time employees, Emerging Infectious Disease fellows, and ORISE trainees; planning and carrying out research to study the responses of human lymphocytes to infection with syphilis and syphilis/HIV coinfection; planning and carrying out research to develop rapid tests for the diagnosis of syphilis; supervising the activities of the syphilis serology reference laboratory; and treponemal and nontreponemal reagent production and evaluation laboratory (for domestic and international manufacturers). Research includes studying HLA types in patients with syphilis to determine if results can be correlated with serologic clinical treatment failure, clinical symptoms, and relapses of secondary symptoms during early latency. Development and evaluation of newer serologic methods for the diagnosis of syphilis. Also serve as director of the WHO Collaborating Center for Reference and Research in Syphilis Serology. As part of these duties, serve as consultant to WHO and PAHO laboratories, and supervising the preparation of samples and reports for CDC/WHO/PAHO Syphilis Serology Proficiency Testing Program for 68 foreign laboratories.

Accomplishments:

1. Managed laboratory database (results of lymphocyte immunophenotyping, syphilis testing, HIV testing) for multi-site (8 sites) cohort study for enhanced vs regular treatment for syphilis in syphilis and syphilis/HIV coinfected patients. Did lymphocyte immunophenotyping for 7 of the 8 sites.

2. Helped develop protocol for Exudative STD study. Developed methodology for determining lymphocyte immunophenotypes in cervical and vaginal samples using three-color flow cytometry.

3. Managed databases for results of Exudative STD study, reported results to Fulton County Health Department and to DSTDP.

4. Suggested and oversaw development of VDRL antigen using synthetic cardiolipin and lecithin, which is resulting in a more stable, sensitive antigen that does not appear to have increased nonspecificity. Resulted in FDA 510(k) clearance, and U.S. and foreign patent applications.

5. Evaluation of Western blot for the diagnosis of syphilis which has resulted in the test becoming a routine test in the Syphilis Diagnostic Reference Laboratory for problem diagnostic cases of syphilis.

6. Have evaluated several new commercial tests for the diagnosis of syphilis. Laboratory personnel in state health departments, VA hospitals, and public hospitals depend on our evaluations, which look at sensitivity and specificity of the tests. Information is disseminated by letters to state health departments, abstracts for meetings, and publications.

7. Continuing support for WHO and PAHO through a proficiency testing program, bench training, reagent evaluation, and consultations. Provided consultation of quality control procedures to one foreign laboratory with on site training. We also provide reference reagents to foreign laboratories when needed. WHO considers our reference reagents to serve as their standards.

8. Consulted with various manufacturers on developing reagents and the process for FDA 510(k) applications. Manufacturers are both domestic and international.

9. Published 9th edition of *A Manual of Tests for Syphilis*.

10. Suggested and oversaw development of rapid tests for the diagnosis of syphilis utilizing a modified cardiolipin. A patent for the modified cardiolipin has gone forward.

11. Served as a member of the teams that went to various High Morbidity Areas (HMAs) for Program Assessments for Syphilis Elimination efforts.

1988-1996. Research Microbiologist, Treponemal Pathogenesis and Immunobiology Branch, Division of Sexually Transmitted Diseases Laboratory Research, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA

Primary responsibilities include planning and independently carrying out, and supervising research to study the response of human lymphocytes to infection with *Treponema pallidum*, and to develop computer assisted methods to study the correlation between lymphocyte subsets, the stage of syphilis, treatment, and HIV infection. Developed procedure for three-color analysis of lymphocytes present in vaginal samples in order to study immune response to exudative STDs (Trichomonas, gonorrhea, Chlamydia, and yeast). Coordinated collection of laboratory results for above two studies. Responsibilities include planning and conducting research on the immunobiology, immunochemistry, and immunology of *Treponema pallidum* subsp. *pallidum* and *pertenue* to identify antigenic determinants. Helped develop standardized procedure for Western blot for

diagnosis of syphilis. Examine street strains of *T. pallidum* by SDS-PAGE, isoelectric focusing and 2-dimensional electrophoresis to determine strain differences and effect of rabbit passage. Participated in large studies to evaluate new tests for syphilis. Prepared samples and reports for CDC/WHO/PAHO Syphilis Serology Proficiency testing program for 57 foreign laboratories.

1980-1988. Microbiologist/Research Microbiologist, Leptospirosis Reference Laboratory, Meningitis and Special Pathogens Branch, Division of Bacterial Diseases, CID, CDC

Responsibilities included primarily research to improve existing tests and develop new diagnostic procedures for leptospirosis, to assess the potential application of state-of-the-art molecular biology techniques to epidemiologic studies of leptospirosis, and to develop improved methods of leptospiral classification. This work involved primarily polypeptide electrophoretic techniques (SDS-PAGE, Western blot) and DNA homology studies, as well as ELISA. Also had reference diagnostic responsibilities for the World Health Organization Collaborating Center for the Epidemiology of Leptospirosis. These responsibilities included serodiagnosis, serotyping of unknown leptospiral isolates from throughout the world, and application of molecular biology techniques such as DNA hybridization.

1975-1980. Microbiologist, Venereal Disease Serology Laboratory, Bacterial Immunology Branch, Bureau of Laboratories, CDC

Planned and independently performed and supervised the performance of duties associated with the conducting of the Syphilis Serology Proficiency Testing Program. This program involved approximately 700 laboratories, including WHO and PAHO laboratories. Duties included selecting serum pools and performing nontreponemal and treponemal tests on these pools, preparing quarterly and annual summary reports, and training. Supervised maintenance of syphilis serum bank.

1974-1975. Medical Technologist, Mycology Laboratory, Third Army Reference Laboratory, Fort McPherson, GA

1974. Chief Bacteriologist, Nolan Biological Labs, Atlanta, GA

1973-1974. Health Standards Survey Officer, Georgia Department Human Resources, Atlanta, GA

1970-1973. Medical Technologist, Microbiology Laboratory, Kettering Memorial Hospital, Kettering, OH

Victoria Pope, Ph.D.
C.V.

Honors:

Supported for Long Term Training	1981, 1982
Superior Work Performance Cash Award	1987
On-The-Spot Cash Award	1993
Group award - NCHSTP Director's Recognition Award for Multisite Cohort Study on enhanced vs standard treatment for persons with syphilis And syphilis/HIV coinfection	1995
On-the-Spot Cash Award for help with Leptospirosis Outbreak in Nicaragua	1996
Group Honor Award - Nicaraguan Epidemic Investigation Group	1997
On-the-Spot Cash Award for helping to organize and run special emphasis panel which resulted in 2 grants being awarded	1998

Memberships in Scientific Societies:

1975 to present: American Society for Microbiology
1977 to 1989: Associate member Sigma Xi
1989 to present: Full member Sigma Xi

1989-90	Banquet Committee
1990-92	Chairperson, Banquet Committee
1991-92	President Elect
1992-93	President
1994-95	Awards Committee
1996-98	Admissions Committee
1996-02	Awards Committee

Miscellaneous:

1996-present:	Chair, Advisory Panel for New Serologic Tests for Syphilis
1996-2001:	Ad hoc Reviewer, American Journal of Tropical Medicine & Hygiene
Reviewer	Objective Review Committee, ASPH/CDC/ATSDR Cooperative Agreement U36/CCU300860-09 Grant Review
Reviewer	Cooperative Agreement Grants, CDC/PHPPO
1996-present	Member, Blood Safety Committee
1998-present	Member, Working group for Elimination of Syphilis Guidelines
1999	Member, Working Group for Reproductive Health Guidelines
2000	Member, MSM Working Group
2000	Reviewer, WHO Bulletin
2003	Editorial Board, European Journal of Clinical Microbiology & Infectious Diseases

Victoria Pope, Ph.D.
C.V.

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ORAL PRESENTATIONS
(Invited talks)

Effect of *Treponema pallidum* and *T. pallidum*-Human Immunodeficiency Virus Coinfection on Peripheral Blood Lymphocyte Subtypes: Results from a Multisite Cohort Study. *In*: (Session 155) Sexually Transmitted Diseases: New Diagnostic Approaches. ASM Annual Meeting, May 18, 1993. Atlanta, GA.

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Syphilis serology: The present and the future. National Laboratory Training Network Meeting, October 25, 2000, Atlanta, GA

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Sexually Transmitted Diseases. Sexton Woods Center biology class. September 12, 2001.

Diagnostic Dilemmas in Syphilis. Univ. Texas at Dallas Medical Center. October 21, 2002

Changing Algorithms in Syphilis Diagnosis, In: (Session 43) Updates in Clinical Microbiology Symposium, September 14, 2003, ICAAC annual meeting, Chicago, IL

Exhibit B

[see attached 1 page]

4 **TITLE**

Work continued from Page 3

PROJECT NO.

BOOK NO.

TEST PROCEDURE FOR VDRL SLIDE TEST.

PROCEDURE AS DESCRIBED IN "MANUAL OF TESTS FOR SYPHILIS" CHAPTER 7 PAGE 80-83.

				VDRL Slide Test				
				Dilutions				
Antiserum	2	4	8	16	32	64	128	Antigen
CDC 97-0014	R	R	R(-)	W	N			CDC 97-0036
	R(-)	R(-)	W(+)	W(-)	N			Pilot I
	R	R	R	W(+)	N			Pilot II
Antiserum	2	4	8	16	32	64	128	Antigen
CDC # 97	R	R	R	R(-)	W(-)	N	N	CDC 97-0036
	R	R	R	W(+)	NR	N	N	Pilot I
	R	R	R	R	W	N	N	Pilot II

Antiserum	Undil	Antigen
# 13	N	CDC
# 16	N	
# 17	N	
# 18	N	
# 19	N	
# 20	N	
# 20 (RPR)	N	
#19 (RPR)	N	

Antiserum	Undil	Antigen
# 13	N	Pilot II
# 16	N	
# 17	N	
# 18	N	
# 19	N	
# 20	N	
# 20 (RPR	N	
#19 (RPR)	N	

FROM THE RESULTS OBTAINED ABOVE - PILOT II CONTAINING THE SYNTHETIC CARDIOLIPIN TETRAMYRISTOYL WAS SELECTED FOR FURTHER STUDIES.

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SIGNATURE [redacted]

Work continued to Page 5

DISCLOSED TO AND UNDERSTOOD BY [redacted]

DATE [redacted]

WITNESS

DATE [redacted]

DATE

Exhibit C

[see attached 1 page]

TEST PROCEDURE FOR THE QUALITATIVE VDRL SLIDE TEST AS DESCRIBED ON "MANUAL OF TEST FOR SYPHILIS" CHAPTER 7 PAGE 80-83.

			Qualitative Test					
				Lecithin				
	Panel	Antigen CDC	C18:1	C18:2	C14:0	C15:0	C16:0	C18:0
Date	Serum	97-0036N	Oleoyl	Linoleoyl	Dimyristoyl	Dipentadecanoyl	Diphytanoyl	Dipalmitoyl
6/14/98	NT-1	R	R	W	$W^{(+)}$	NR	N	W
Cardiolipin	NT-2	R	$W^{(+)}$	N	$W_{(-)}$	N	N	W
C14:0	NT-3	R	$R_{(-)}$	N	$W^{(+)}$	N	N	N
	NT-4	$R_{(-)}$	$W^{(+)}$	N	$W^{(+)}$	N	N	N
	NT-5	R	$W^{(+)}$	N	$W_{(-)}$	N	N	N
	NT-6	R	$R_{(-)}$	N	$W^{(+)}$	N	N	N
	NT-7	R	W	N	$W_{(-)}$	N	N	N

RESULTS:

THE QUALITATIVE TEST RESULTS OBTAINED WITH DIFFERENT LECITHINS WERE NOT COMPARABLE TO THE REFERENCE CDC VDRL ANTIGEN.

SIGNATURE [redacted]			DATE [redacted]
DISCLOSED TO AND UNDERSTOOD BY [redacted]	DATE [redacted]	WITNESS	DATE

Exhibit D

[see attached 4 pages]

			Qualitative Test			
Date	Panel	Antigen CDC	Cardiolipin, 0.03%	Frozen	Antigen CDC	Cardiolipin, 0.03%
7/15/98	Serum	97-0036N	Lecithin 0.14%	Serum	97-0036N	Lecithin 0.14%
	NT-1	R	R	F-1	R	R
	NT-2	R	R	F-2	R	R
	NT-3	R(-)	R	F-3	N	N
	NT-4	R(-)	R(-)	F-4	W(+)	R
	NT-5	R	W(+)	F-5	R(-)	R
	NT-6	R	R	F-6	N	N
	NT-7	R(-)	R(-)	F-7	N	N
	NT-8	NR	NR	F-8	R(-)	R
	NT-9	N	N	F-9	N	N
	NT-10	N	N	F-10	N	N
	NT-11	N	N	F-11	R(-)	R
	NT-12	N	N	F-12	R(-)	R
	NT-13	N	N	F-13	R	R
	NT-14	R	R	F-14	R(-)	R
	NT-15	R	R	F-15	R	R
	NT-16	W(-)	W	F-16	R	R
	NT-17	NR	NR	F-17	R(-)	R
	NT-18	R(-)	W(+)	F-18	R(-)	R
	NT-19	W	W	F-19	N	N
	NT-20	R(-)	R(-)	F-20	N	N

RESULTS:

RESULTS OF THE QUALITATIVE TEST INDICATES THAT CARDIOLIPIN TETRAMYRISTOYL AT A CONCENTRATION OF 0.03 % WHEN ADDED TO THE ASYMETRIC 1-PALMITOYL-2-OLEOYL (16:0 18:1) LECITHIN AT A CONCENTRATION OF 0.14 % OR 0.16 % GIVES A REACTION ~~AN~~ EQUIVALENT OR BETTER THAN THE CDC REFERENCE VDRL STANDARD -

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TEST PROCEDURE FOR THE QUANTITATIVE VDRL SLIDE TEST AS DESCRIBED ON "MANUAL OF TEST FOR SYPHILIS" CHART. 15. QUALITY CONTROL PAGE 167 - 170.

Date 8/26/98			Quantitative Test					
Serum	2	4	8	16	32	64	128	Antigen
98-6-18	R	R	W(+)	N	N			CDC
	R(+)	R(+)	R(-)	N	N			Cardio 0.02% Lect. 0.11%
	R(+)	R(+)	R(-)	N	N			Cardio 0.03% Lect. 0.14%
	R	R(-)	Rm	N	N			RPR
Serum	2	4	8	16	32	64		Antigen
98-6-19	W(+)	W(-)	N	N	N	N		CDC
	R(+)	R(-)	NR	N	N	N		Cardio 0.02% Lect. 0.11%
	R(+)	R(-)	NR	N	N	N		Cardio 0.03% Lect. 0.14%
	R	R(-)	Rm	N	N			RPR
Serum	2	4	8	16	32	64	128	Antigen
98-6-23	R	R	R	R	W(+)	N	N	CDC
	R	R	R	R(+)	R	W	N	Cardio 0.02% Lect. 0.11%
	R	R	R	R(+)	R	W	N	Cardio 0.03% Lect. 0.14%
	R	R	R	R	R(-)	Rm	N	RPR
Serum	2	4	8	16	32	64		Antigen
98-6-41	R	R	R	R(-)	W	N		CDC
	R	R	R	R	W(+)	N		Cardio 0.02% Lect. 0.11%
	R	R	R	R(+)	W(+)	N		Cardio 0.03% Lect. 0.14%
	R	R	R	R	R(-)	Rm		RPR
Serum	2	4	8	16	32	64	128	Antigen
98-6-47	R	R	R	R(-)	W(+)	N	N	CDC
	R	R	R(+)	R(+)	R	W(-)	N	Cardio 0.02% Lect. 0.11%
	R	R	R(+)	R(+)	R	W	N	Cardio 0.03% Lect. 0.14%
	R	R	R	R(-)	R(-)	Rm	N	RPR
Serum	2	4	8	16	32	64		Antigen
98-6-53	R(-)	W	N	N	N	N		CDC
	R(+)	R	W(-)	N	N	N		Cardio 0.02% Lect. 0.11%
	R(+)	R(+)	W(+)	N	N	N		Cardio 0.03% Lect. 0.14%
	R	R(-)	Rm	N	N	N		RPR
Serum	2	4	8	16	32	64		Antigen
98-6-44	R	R	W(+)	W(-)	N	N		CDC
	R(+)	R	R(-)	W	N	N		Cardio 0.02% Lect. 0.11%
	R(+)	R	R(-)	W	N	N		Cardio 0.03% Lect. 0.14%
	R	R	R(-)	Rm	N	N		RPR

Serum	1	2	4	8				Antigen
98-6-59	W(+)	W	N	N				CDC
	R(-)	W(-)	NR	N				Cardio 0.02% Lect. 0.11%
	R	R(-)	W(-)	N				Cardio 0.03% Lect. 0.14%
	R	R(-)	Rm	N				RPR
Serum	2	4	8	16	32	64		Antigen
98-6-60	R	W(+)	W(-)	N	N			CDC
	R(+)	R	W(+)	W	N			Cardio 0.02% Lect. 0.11%
	R(+)	R	W(+)	W	N			Cardio 0.03% Lect. 0.14%
	R	R(-)	Rm	N	N			RPR
Serum	2	4	8	16	32	64		Antigen
98-6-65	R	R(-)	NR	N	N			CDC
	R	R	W(+)	W	N			Cardio 0.02% Lect. 0.11%
	R	R	W(+)	W	N			Cardio 0.03% Lect. 0.14%
	R	R(-)	Rm	N	N			RPR
Serum	1	2	4	8				Antigen
98-6-66	W(+)	N	N	N				CDC
	R(-)	NR	N	N				Cardio 0.02% Lect. 0.11%
	R	NR	N	N				Cardio 0.03% Lect. 0.14%
	Rm	N	N	N				RPR
Serum	1	2	4	8				Antigen
98-6-67	R(-)	W(+)	N	N				CDC
	R(+)	R(-)	W(-)	N				Cardio 0.02% Lect. 0.11%
	R(+)	R	W(-)	N				Cardio 0.03% Lect. 0.14%
	R(-)	Rm	N	N				RPR
Serum	2	4	8	16	32	64		Antigen
98-6-74	R	R	R	W(+)	N	N		CDC
	R	R	R	R(-)	N	N		Cardio 0.02% Lect. 0.11%
	R	R	R	R(-)	N	N		Cardio 0.03% Lect. 0.14%
	R	R	R	R	Rm	N		RPR
Serum	2	4	8	16	32	64		Antigen
98-6-75	R	R	W(+)	NR	N			CDC
	R	R	R(-)	W(-)	N			Cardio 0.02% Lect. 0.11%
	R	R	R(-)	NR	N			Cardio 0.03% Lect. 0.14%
	R	R	R	Rm	N			RPR

ENDPOINT TITER COMPARISON OF RPR WITH A 100 ML PILOTS OF SYNTHETIC VDRL - PAGE 27 AND CDC REFERENCE VDRL ANTIGEN -

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Serum	1	2	4	8				Antigen
98-6-76	NR	N	N	N				CDC
	W	NR	N	N				Cardio 0.02% Lect. 0.11%
	W	NR	N	N				Cardio 0.03% Lect. 0.14%
	Rm	N	N	N				RPR

Serum	2	4	8	16	32	64	128	Antigen
98-6-77	R	R	R	R	$R_{(-)}$	W	N	CDC
	R	R	R	R	$R_{(-)}$	W	N	Cardio 0.02% Lect. 0.11%
	R	R	R	R	$R_{(-)}$	W	N	Cardio 0.03% Lect. 0.14%
	R	R	R	R	R	$R_{(-)}$	Rm	RPR

Serum	1	2	4	8				Antigen
98-6-80	R	$W_{(-)}$	N	N				CDC
	R	$R_{(-)}$	NR	N				Cardio 0.02% Lect. 0.11%
	R	R	NR	N				Cardio 0.03% Lect. 0.14%
	R	R	Rm	N				RPR

Serum	1	2	4	8				Antigen
98-6-81	W	N	N	N				CDC
	$R_{(-)}$	$W^{(*)}$	N	N				Cardio 0.02% Lect. 0.11%
	W	$R_{(-)}$	N	N				Cardio 0.03% Lect. 0.14%
	R	Rm	N	N				RPR

Serum	2	4	8	16	32	64		Antigen
98-6-82	R	R	R	R	W	N		CDC
	R	R	R	R	$W^{(*)}$	N		Cardio 0.02% Lect. 0.11%
	R	R	R	R	$R_{(-)}$	N		Cardio 0.03% Lect. 0.14%
	R	R	R	R	Rm	N		RPR

Serum	1	2	4	8				Antigen
98-6-85	W	N	N	N				CDC
	R	NR	N	N				Cardio 0.02% Lect. 0.11%
	R	W	N	N				Cardio 0.03% Lect. 0.14%
	$R_{(-)}$	Rm	N	N				RPR

Serum	1	2	4	8				Antigen
98-6-86	W	N	N	N				CDC
	R	W	N	N				Cardio 0.02% Lect. 0.11%
	R	$W^{(*)}$	N	N				Cardio 0.03% Lect. 0.14%
	R	Rm	N	N				RPR

Serum	1	2	4	8				Antigen
98-6-87	$R_{(-)}$	$W^{(*)}$	N	N				CDC
	R	$R_{(-)}$	W	N				Cardio 0.02% Lect. 0.11%
	R	R	W	N				Cardio 0.03% Lect. 0.14%
	R	R	Rm	N				RPR

Serum	1	2	4	8	16			Antigen
98-6-90	R	$R_{(-)}$	$W_{(-)}$	N	N			CDC
	R	R	W	N	N			Cardio 0.02% Lect. 0.11%
	R	R	$W^{(*)}$	N	N			Cardio 0.03% Lect. 0.14%
	R	R	R	Rm	N			RPR

Serum	2	4	8	16	32	64		Antigen
98-6-91	R	$R_{(-)}$	$W_{(-)}$	NR	N			CDC
	R	R	$R_{(-)}$	$W_{(-)}$	N			Cardio 0.02% Lect. 0.11%
	R	R	$R_{(-)}$	$W_{(-)}$	N			Cardio 0.03% Lect. 0.14%
	R	R	$R_{(-)}$	Rm	N			RPR

Serum	2	4	8	16	32			Antigen
98-6-92	$R_{(-)}$	W	N	N				CDC
	R	$W^{(*)}$	$W_{(-)}$	N				Cardio 0.02% Lect. 0.11%
	R	$R_{(-)}$	$W_{(-)}$	N				Cardio 0.03% Lect. 0.14%
	R	R	Rm	N				RPR

Serum	2	4	8	16	32			Antigen
98-6-99	R	R	$R_{(-)}$	W	N			CDC
	R	R	R	$W^{(*)}$	N			Cardio 0.02% Lect. 0.11%
	R	R	R	$W^{(*)}$	N			Cardio 0.03% Lect. 0.14%
	R	R	R	Rm	N			RPR

Serum	2	4	8	16	32	64	128	Antigen
98-6-102	R	R	R	R	$R_{(-)}$	$W^{(*)}$	N	CDC
	R	R	R	R	R	$R_{(-)}$	N	Cardio 0.02% Lect. 0.11%
	R	R	R	R	R	R	NR	Cardio 0.03% Lect. 0.14%
	R	R	R	R	R	$R_{(-)}$	Rm	RPR

Serum	2	4	8	16	32	64	128	Antigen
98-6-[illegible]	R	R	R	R	W	N	N	CDC
	R	R	R	R	$W^{(*)}$	N	N	Cardio 0.02% Lect. 0.11%
	R	R	R	R	$W^{(*)}$	N	N	Cardio 0.03% Lect. 0.14%
	R	R	R	R	R	Rm	N	RPR

Serum	2	4	8	16	32	64		Antigen
98-6-106	R	R	R	R	$W^{(*)}$	N		CDC
	R	R	R	R	$R_{(-)}$	N		Cardio 0.02% Lect. 0.11%
	R	R	R	R	$R_{(-)}$	$W_{(-)}$		Cardio 0.03% Lect. 0.14%
	R	R	R	R	R	Rm		RPR

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RESULTS:

SYNTHETIC VDRL IS ONE DOUBLING AND ONE HALF DILUTION GREATER THAN THE CDC REFERENCE VDRL ANTIGEN IN 89.5% OF THE QUANTITATIVE SAMPLES TESTED.

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QUALITATIVE TEST PROCEDURE COMPARISON OF MHA-TP WITH RPR CDC VDRL REFERENCE ANTIGEN & SYNTHETIC VDRL ANTIGEN.

Date 9/10/98	Serum	MHA-TP	RPR	CDC	Card 0.02% Lecit. 0.11 %	Card 0.03% Lecit. 0.14 %		Qualitative Test Serum	MHA-TP	RPR	CDC	Card 0.02% Lecit. 0.11 %	Card 0.03% Lecit. 0.14 %
1	98-6-24	2+	Rm	N	NR	NR	27	98-6-93	3+	Rm	N	$R_{(-)}$	R
2	98-6-26	N	Rm	NR	$W_{(-)}$	$W_{(-)}$	28	98-6-94	N	$Rm_{(-)}$	N	N	N
3	98-6-30	3+	Rm	NR	W	W	29	98-6-97	3+	Rm	N	W	$W^{(+)}$
4	98-6-33	2+	Rm	N	$W_{(-)}$	$W_{(-)}$	30	98-6-98	3+	Rm	$W^{(-)}$	$R_{(-)}$	R
5	98-6-35	N	Rm	N	$W_{(-)}$	$W_{(-)}$	31	98-6-100	plus-minus	Rm	$W^{(-)}$	$R_{(-)}$	R
6	98-6-37	4+	Rm	$W_{(-)}$	R	R	32	98-6-101	2+	Rm	N	$W^{(+)}$	$R_{(-)}$
7	98-6-45	N	$Rm_{(-)}$	NR	NR	NR	33	98-6-114	3+	Rm	N	W	$W^{(+)}$
8	98-6-46	3+	Rm	N	NR	NR	34	98-6-116	3+	Rm	N	W	$W^{(+)}$
9	98-6-48	2+	Rm	N	$W_{(-)}$	W	35	98-6-117	2+	$Rm^{(+)}$	$W^{(+)}$	R	$R^{(+)}$
10	98-6-49	3+	Rm	$W_{(-)}$	W	$W^{(+)}$	36	98-6-119	3+	$Rm^{(+)}$	N	$W^{(+)}$	$R_{(-)}$
11	98-6-50	3+	$Rm_{(-)}$	N	W	$W^{(+)}$	37	98-6-123	plus-minus	$Rm_{(-)}$	N	N	N
12	98-6-51	3+	Rm	N	W	$W^{(+)}$	38	98-6-126	3+	Rm	N	NR	NR
13	98-6-52	3+	$Rm_{(-)}$	N	W	$W^{(+)}$	39	98-6-129	3+	Rm	N	W	$W^{(+)}$
14	98-6-56	3+	Rm	NR	$W^{(+)}$	$R_{(-)}$	40	98-6-130	3+	Rm	$W_{(-)}$	$R_{(-)}$	$R^{(+)}$
15	98-6-61	4+	Rm	N	W	$W^{(+)}$	41	98-6-137	3+	Rm	N	N	N
16	98-6-62	plus-minus	$Rm_{(-)}$	N	NR	$W_{(-)}$	42	98-6-141	3+	$Rm_{(-)}$	N	N	N
17	98-6-63	3+	Rm	N	$W^{(+)}$	$R_{(-)}$	43	98-6-142	1+	NR	N	N	N
18	98-6-64	3+	$Rm_{(-)}$	N	NR	$W_{(-)}$	44	98-6-143	3+	Rm	N	$W_{(-)}$	W
19	98-6-69	3+	Rm	N	$W^{(+)}$	R	45	98-6-145	4+	Rm	N	W	$R_{(-)}$
20	98-6-70	3+	Rm	N	NR	$W_{(-)}$	46	98-6-146	3+	Rm	N	NR	$W_{(-)}$
21	98-6-71	2+	Rm	N	NR	$W_{(-)}$	47	98-6-148	3+	Rm	$W_{(-)}$	$R_{(-)}$	R
22	98-6-72	3+	$Rm^{(+)}$	R	$R_{(-)}$	R	48	98-6-149	1+	NR	NR	W	W
23	98-6-73	3+	Rm	N	W	$W^{(+)}$	49	98-6-150	3+	Nr	N	NR	$W_{(-)}$
24	98-6-79	plus-minus	Rm	N	W	$W^{(+)}$	50	98-6-151	3+	$Rm_{(-)}$	NR	$W_{(-)}$	W
25	98-6-88	3+	$Rm^{(+)}$	N	$W^{(+)}$	$R_{(-)}$	51	98-6-152	3+	Rm	$W_{(-)}$	$W^{(+)}$	$R_{(-)}$
26	98-6-89	3+	Rm	N	W	$W^{(+)}$	52	98-6-153	N	N	N	N	N

9/10/98	Serum	MHA-TP	RPR	CDC	Card 0.02% Lecit. 0.11 %	Card 0.03% Lecit. 0.14 %		Serum		RPR	CDC	Card 0.02% Lecit. 0.11 %	Card 0.03% Lecit. 0.14 %
53	98-6-155	2+	$Rm_{(-)}$	$W_{(-)}$	$W^{(+)}$	$R_{(-)}$							
54	98-6-156	3+	$Rm^{(+)}$	W	$R_{(-)}$	$R^{(+)}$							
55	98-6-157	4+	$Rm^{(+)}$	W	$R_{(-)}$	$R_{(-)}$							
56	98-6-158	N	NR	N	N	N							
57	98-6-162	3+	Rm	N	$W_{(-)}$	W							
58	98-6-168	4+	$Rm^{(+)}$	$W^{(+)}$	$R_{(-)}$	R							
59	98-6-170	3+	NR	N	NR	NR							
60	98-6-171	4+	$Rm^{(+)}$	NR	$R_{(-)}$	R							

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